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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,230	04/02/2004	Victor I. Chornenky	1004.013	3048

7590 10/17/2006

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,230	CHORNENKY ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 8/29/2006.

2. In the reply the Applicant filed formal drawings obviating the objection to the drawings and objection to the specification by removing reference numeral 62 in Fig 1.

3. Additionally, the Applicant amended the title to obviate the objection that the title was not descriptive.

4. Claim 1 was amended to fix grammatical errors.

5. Thus, claims 1-8 are pending for examination on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiss (6402734). Weiss discloses a minimally invasive therapeutic agent delivery system (Fig 4) comprising a reservoir (12) comprising a therapeutic agent (col 4, ln 14); an elongate probe (6) having a passage therein, the probe configured to conform at least in part to the curvature of the eye (col 3, lns 50-64) and has a proximal probe end (Fig 3) and a distal probe end (Fig 3) including a distal probe opening (Fig 3); a therapeutic agent

delivery apparatus (4) being fluidly connected to said reservoir (Fig 4; col 3, lns 50-64; col 4, lns 11-21) and configured to be disposed within said passage (Fig 3) and movable between a retracted inoperative position within said probe (col 3, lns 50-64) and an extended operational position (col 3, lns 50-64), wherein movement of said delivery apparatus from the inactive to the operational position enables the therapeutic agents to be dispensed from said reservoir through said distal probe opening into the eye (col 3, lns 50-64; col 4, lns 11-21; col 5, lns 23-38); a handle (1a) attached to said probe proximal end (Fig 1); the reservoir being attached to said handle (Fig 4); the therapeutic agent delivery apparatus comprises an elongate needle (4; col 3, lns 21-32).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaleski (5242449) in view of Yaacobi et al (6413245). Zaleski discloses a minimally invasive therapeutic agent delivery system (11) comprising a reservoir (77) comprising a therapeutic agent (col 1, lns 15-23); an elongate probe (27) and has a proximal probe end (37; Fig 2) and a distal probe end (29; Fig 2) including a distal probe opening (33; Fig 2); a therapeutic agent delivery apparatus (37) being fluidly connected to said reservoir (Fig 1, 2) and configured to be disposed within said passage (Fig 2) and movable between a retracted inoperative position within said probe (Fig 2) and an

extended operational position (Fig 3), wherein movement of said delivery apparatus from the inactive to the operational position enables the therapeutic agents to be dispensed from said reservoir through said distal probe opening into the eye (col 6, lns 43-61; col 9, lns 19-33; col 12, lns 28-39 & lns 49-51); a handle (47) attached to said probe proximal end; the reservoir being attached to said handle (77; 47; Fig 1); the therapeutic agent delivery apparatus comprises an elongate needle (29); wherein said passage bends said needle (col 5, lns 25-28) when said needle is moved from its retracted to its extended position (Fig 2, 3, 6); and said probe includes a probe positioning portion (29) at said distal probe end.

10. However, Zaleski does not disclose the elongate probe configured to conform at least in part to the curvature of the eye and the probe distal end having an eye-surface engaging surface configured to conform to the surface of the eye with the probe passage including a portion conforming to the surface of the eye and a portion that angles toward the eye such that said distal probe opening is in said eye-surface engaging surface.

11. Yaacobi et al teaches that it is known to have the elongate probe (58) configured to conform at least in part to the curvature of the eye (52, Fig 2) and the probe distal end having an eye-surface engaging surface (52, Fig 2) configured to conform to the surface of the eye with the probe passage including a portion conforming to the surface of the eye (52) and a portion that angles toward the eye (64) such that said distal probe opening is in said eye-surface engaging surface (64, Fig 2) for the purpose of delivering ophthalmically acceptable pharmaceutically active agents to the back of the eye

proximate to the macula (col 1, lns 8-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the probe as taught by Zaleski with the eye-conforming probe as taught by Yaacobi et al for the purpose of delivering ophthalmically acceptable pharmaceutically active agents to the back of the eye proximate to the macula (col 1, lns 8-14).

Response to Arguments

12. Applicant's arguments filed 8/29/2006 have been fully considered but they are not persuasive.

13. The Applicant argues against the 35 USC 102(e) rejection of claims 1-4 to Weiss by stating:

i. That the Examiner has characterized the claim recitation improperly by not stating that the probe itself is configured to conform at least in part to the curvature of the eye. (Remarks, pg 7, paragraph 4)

ii. The Weiss Figures do not show a probe configured to conform to the eye's curvature. (Remarks, pg 8, paragraph 1)

iii. That the Weiss system can only be said to be "minimally invasive" only to the extent of comparison of its use to past practices; because while the Weiss system requires a small incision to be made, the Applicant's invention does not require any incisions. (Remarks, pg 8, paragraph 3-5)

14. In response to the Applicant's argument that (i), the Examiner notes that it was the Examiner's intention all along to state that the probe is configured to conform to the curvature of the eye. The Examiner notes that the office action correctly stated "a probe

having a passage therein configured to conform at least in part to the curvature of the eye"; wherein, it is still clear that the probe has a passage and conforms at least in part to the curvature of the eye.

15. In response to the Applicant's argument that (ii), the Examiner notes that in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. See *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. In the instant case, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner notes that the Applicant has not recited any necessary size or angles to provide structural necessities the probe must have to conform *at least in part* to the curvature of the eye. Furthermore, the use of the terms "at least in part" only necessitate that any part, no matter how small, conform to the curvature under any circumstances to the curvature of the eye. In short, the claim language is very broad and the Applicant is suggested to further define the probe's curvature in relation to the curvature of the eye. As it stands, the curvature of the probe is clearly capable of interacting with the eye in a manner as to conform to the curvature of the eye over at least a portion of the probe.

16. In response to the Applicant's argument that (iii), the Examiner notes that the features upon which applicant relies (i.e., that the Applicant's invention does not make an incision) are not recited in the rejected claim(s). Although the claims are interpreted

in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Examiner suggests that the Applicant incorporate into claim language the arguments the Applicant uses. As it stands, the features relied upon are not in the claims. Furthermore, the Examiner notes that it is well known in the medical art that the term "minimally invasive" encompasses surgical incisions. Often, the term "minimally invasive" is utilized to describe a medical system that performs a very small incision compared to past practices wherein the procedure required much more invasive actions. Thus, the Examiner maintains that the Weiss system is properly characterized as being minimally invasive even though Weiss's system makes an incision.

17. The Applicant argues against the 35 USC 103(a) rejection of claims 1-8 to Zaleski in view of Yaacobi et al by stating:

> iv. That Zaleski does not teach or suggest drug delivery as a function of the invention and that Yaacobi teaches drug delivery on the outer surface of the sclera. Thus, there is no motivation to combine the references except for impermissible highsight. (Remarks, pg 9, paragraph 4-6)
>
> v. The function and design of the Zaleski slider are different from the Applicant's and being soft, it cannot serve as a needle and cannot pierce the sclera. (Remarks, pg 10, paragraph 2-4)

vi. The combination of references does not teach that the passage through which the needle travels redirects the direction of the needle as it is advances and retracted. (Remarks, pg 11, paragraph 3)

18. In response to applicant's argument (iv) that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

19. Additionally, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Zaleski does disclose being used for irrigating the eye during ophthalmic surgery using irrigation fluid. Irrigation fluid is fully capable as acting as a therapeutic agent as the fluid assists to cure, dissolve, or remove particles from the eye. The Examiner further notes that the Applicant does not claim a specific drug or drug formulation. Furthermore, Yaacobi does disclose an apparatus and specific structure that does pierce and penetrate into

eye tissues (col 6, lns 1-4) and is designed to reach specific portions of the eye by conforming to the curvature of the eye. Thus, the Examiner finds motivation to combine Zaleski and Yaacobi, which are analogous art pertaining to performing surgical procedures introducing therapeutic fluid to the eye and that such a combination is not impermissible hingsight (For motivation, see pervious Office Action, pg 6, paragraph 1).

20. In response to applicant's argument (v), the Examiner notes that in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., piercing of the sclera) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, the Applicant has not provided any structure to the needle and thus has not required the needle to have a sufficient hardness to be capable of performing the recited subject matter. The Examiner notes that Webster's Dictionary defines "needle" as: "a slender hollow instrument for introducing the material into or removing material from the body parenterally". Thus, the Examiner maintains that the Applicant's claimed subject matter does not distinguish over Zaleski.

In response to applicant's argument (vi), the Examiner notes that the needle (29) of Zaleski is bendable will conform to the direction of the passage as it is advanced and retracted (col 5, lns 25-28). Again, the Examiner notes that the Applicant has not claimed a sharp metal needle piercing the sclera on a predetermined depth and

delivering drugs. The Examiner suggests that the Applicant add such language into the claim to obviate the rejection.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bos (2004/0167480); Giungo (6036678); del Cerro et al (5273530); Hughes (6514238); Helfgott et al (4530359); Schlegel (4706669).

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

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